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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,561	01/30/2002	James E. Dvorsky	VI/99-020	7657

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EXAMINER

PASS, BARRY

ART UNIT PAPER NUMBER

3737

DATE MAILED: 06/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/060,561

Applicant(s)

DVORSKY ET AL.

Examiner

Barry Pass

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 14, 15, 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-13 and 16-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

This application contains claims directed to the following patentably distinct species of the claimed invention:

First embodiment (Claims 1-6) is drawn to an imaging system with multiple sources of imaging energy, including x-ray or gamma-ray and ultrasound, and one detector, classified in class 600 subclass 438.

Second embodiment (claims 7-13, 16-24 and Fig. 1) is drawn to a system and method of detecting extravasation during using one source of energy, x-ray, gamma-ray or ultrasound, and one detector, classified in class 600, subclass 300.

Third embodiment (claims 14-15, 25-26) is drawn to a system and method of detecting extravasation during an imaging procedure and using multiple sources of imaging energy and multiple detectors classified in class 600, subclass 431.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Gregory L. Bradley, Registration No. 34,299, on May 28, 2003 a provisional election was made with traverse to prosecute the invention of embodiment 2, claim 7-13 and 16-24. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-6, 14-15 and 25-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

#### ***Examiner's Amendment***

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR

1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Gregory L. Bradley on May 28, 2003.

The application has been amended as follows:

Claim 8, line 3, delete "second imaging" insert --first-- therefore;

*Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 7, 16, 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Segall et al. US 4,923,442. Segall et al. discloses (column 3, lines 24-48) a system and method for detecting leakage of blood from blood vessels during surgical procedures by adding contrast media detectable by x-ray to blood substitutes administered during the procedures.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 7-13, 16-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Karellas et al. US 2002/0172323. Karellas et al. discloses a system and method for detecting extravasation (abstract) using a source of x-rays or ultrasound [0008] and a sensor mounted in a housing [0020] to image an injection site during the injection procedure (Fig. 1); contrast enhancement [0002]; establishing a baseline signal [0025] and a threshold value [0026] for the detected signal; electronic control of a power injector [0019] with electronic or visual indicators of extravasation [0019].

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Segall et al. Segall et al. discloses (column 3, lines 24-48) a system and method for detecting leakage of

blood from blood vessels during surgical procedures by adding contrast media detectable by x-ray to blood substitutes administered during the procedures. Segall et al does not teach detection of extravasation with ultrasound. Without the criticality specified by the applicant over which energy source to use, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use x-ray or ultrasound as well-recognized functionally equivalent methods for monitoring a region of interest.

9. Claims 8-10, 12, 13, 17-21, 23, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segall et al. in view of Uber III, et al. US 5,954,668. Segall et al. teach a system and method for detecting extravasation as recited in claims 7, 11, 16, and 22 above. Segall et al. does not teach detection of extravasation during a surgical procedure that may require an alarm system. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the system and method of Segall et al. to detect extravasation during an injection procedure. Further, Segall et al. does not teach an alarm system with baseline and threshold values for measured signals. Uber, III et al. teach a system and method to detect extravasation during an injection procedure using an alarm system with baseline and threshold values for measured signals. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use with the system and method to detect extravasation as taught by Segall et al. the technique, well known in the art and taught by Uber, II et al., of using an alarm system with baseline and threshold values for measured signals during an injection procedure.

10. Claims 23, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karellas et al. Karellas et al. discloses a system and method for detecting extravasation (abstract) using a source of x-rays or ultrasound [0008] and a sensor mounted in a housing [0020] to image an injection site during the injection procedure (Fig. 1); contrast enhancement [0002]; establishing a baseline signal [0025] and a threshold value [0026] for the detected signal; electronic control of a power injector [0019] with electronic or visual indicators of extravasation [0019]. In regard to claim 23, inherent to the interaction of x-rays with the contrast medium and tissues at the site are reflection, scatter and absorption of the incident radiation. In regard to claim 24, without the criticality specified by the applicant as to which functional relationship the measured signal has with the amount of radiation reflected, scattered and absorbed, the choice of the functional relationship for the detection system would have been a matter of design choice for one of ordinary skill in the art at the time the invention was made.

### *Conclusion*

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Mockros et al. et al. US 5,957,950. Mockros et al. discloses a system and method for detecting vascular trauma during angioplasty that results in extravasation of contrast material using ultrasound imaging and, alternatively, by monitoring acoustic emissions from deformation of vascular tissue.


Atkins et al. US 4,877,034 teaches a non-invasive system and method for detecting tissue infiltration during administration of fluids using electromagnetic radiation, a baseline, threshold, alarm system and means for terminating the infusion of fluids.




12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barry Pass whose telephone number is (703) 305-0726. The examiner can normally be reached on Monday-Friday, 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on (703) 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0873.

Barry Pass   
May 29, 2003

  
Marvin M. Lateef  
Supervisory Patent Examiner  
Group 3700